DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Biomet Manufacturing Corporation
Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K130390
Trade/Device Name: Comprehensive Convertible Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT, PAO, MBF
Dated: August 21, 2013
Received: August 22, 2013

Dear Ms. Beres:

This letter corrects our substantially equivalent letter of October 9, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130390

Device Name: Comprehensive Convertible Glenoid

Indications For Use:

Anatomic Applications

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
6. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Reverse Applications

The Comprehensive Reverse Shoulder is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Comprehensive Convertible Glenoid Baseplate components are intended for cementless applications with the addition of screw fixation.

Interlok finish humeral stems are intended for cemented use and the MacroBond coated humeral stems are intended for press-fit or cemented application. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopaedic Devices

BIOMET
MANUFACTURING CORP.

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

SUBMITTER INFORMATION		
Name	Biomet Manufacturing Corp.	
Address	56 East Bell Drive Warsaw, IN 46582	
Phone number	(574) 267-6639	
Fax number	(574) 371-1027	
Establishment Registration Number	1825034	
Name of contact person	Patricia Sandborn Beres Senior Regulatory Specialist Biomet Manufacturing Corp.	
Date prepared	August 16, 2013	
NAME OF DEVICE		
Trade name	Comprehensive® Convertible Glenoid	
Common name	Glenoid prosthesis	
Classification name	**Regulation**	**Product Code**
Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis	21 CFR 888.3660	KWS
Shoulder joint metal/polymer non-constrained cemented prosthesis	21 CFR 888.3650	KWT
Shoulder joint metal/polymer (+additive) semi-constrained cemented prosthesis	21 CFR 888.3660	PAO
Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis	21 CFR 888.3670	MBF
Classification panel	Orthopedics	
Legally marketed device(s) to which equivalence is claimed	SMR™ Modular Glenoids (K113254) BioModular® Shoulder System (K992119, K030710) Comprehensive® Reverse Shoulder (K080642, K120121)	
Reason for 510(k) submission	New device	
Device description	The Comprehensive Convertible Glenoid Baseplate is round, truncated on the anterior and posterior sides. The baseplate features a medial boss through which a Central Screw is placed to hold the component in place. The back surface of the component is porous coated. There are two peripheral screw holes through the baseplate. Screws are available in both locking and non-locking styles. When used with a polyethylene liner, the construct is designed to articulate with a metallic humeral head attached to a humeral stem in a traditional, anatomic total shoulder configuration. Should revision to a reverse shoulder construct be desirable, the polyethylene liner can be removed without removal of the baseplate and replaced with a glenosphere component.	

OCT 0 9 2013

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574 267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Indications for use	Anatomic Applications 1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis. 2. Rheumatoid arthritis. 3. Revision where other devices or treatments have failed. 4. Correction of functional deformity. 5. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate. 6. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate. Reverse Applications The Comprehensive Reverse Shoulder is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary. The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. Comprehensive Convertible Glenoid Baseplate components are intended for cementless applications with the addition of screw fixation. Interlok finish humeral stems are intended for cemented use and the MacroBond coated humeral stems are intended for press-fit or cemented application. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

	Comprehensive® Convertible Glenoid	**SMR™ Modular Glenoid**	**Bio-Modular® Glenoid**	**Comprehensive® Reverse Shoulder**
Material	Ti-6Al-4V UHMWPE	Ti-6Al-4V UHMWPE	Ti-6Al-4V UHMWPE	Ti-6Al-4V
Profiles	Truncated round	Truncated round	Pear shaped	Round
Sizes	23 x 28mm	Small-R, Small, Standard, Large	Small, Medium, Large	25 and 28mm
Poly/Tray Attachment	Four pegs	Snap-fit Central lug	One peg	NA
Glenosphere Attachment	Taper Adapter	Taper Post	NA	Taper Adapter
Surface Coatings	Porous plasma spray	Porous plasma spray	Porous plasma spray	Porous plasma spray with HA
Features	Central screw boss Two screw holes	Central Post Two screw holes	Central post Two screw holes	Medial Boss w/Screw Four screw holes

PERFORMANCE DATA	
Non-Clinical Tests Conducted For Determination Of Substantial Equivalence	
Range of motion	Axial separation of tapers
Torsional separation of tapers	Axial pull-off of bearings
Shear separation of bearings	FEA Stress Simulation
Initial fixation	Disassociation
Shear Load to Failure	
Clinical Tests Conducted for Determination of Substantial Equivalence and/or of Clinical Information	
No clinical data submitted	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
No clinical data was necessary for a determination of substantial equivalence. The results of testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.	